DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 29, 2014

Degania Silicone, Ltd.
Zoya Lee
RA CO
Degania Bet
Emek Hayarden, 151300
Israel

Re: K143378
Trade/Device Name: AQUARIUS™ Gastrostomy Replacement Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PIF
Dated: November 12, 2014
Received: November 25, 2014

Dear Zoya Lee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143378

Device Name
AQUARIUS™ Gastrostomy Replacement Tube

Indications for Use *(Describe)*

AQUARIUS™ Gastrostomy Replacement Tube is intended for use in a well-established gastrostomy tract for feeding and/or administration of medications. May be used for gastric decompression.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Premarket Notification Summary under 21 CFR § 807.92

a) Type of 510(k) submission: Special

b) Common name: Gastrostomy Replacement Tube

c) Device trade name: AQUARIUSÊ Gastrostomy Replacement Tube

d) Classification Panel: 21 CFR 876.5980

e) Classification Name: Gastrointestinal tube and accessories

f) Class: II

g) Product code: PIF

h) **Predicate / Unmodified device:** 510(k) **K070124**

i) **Reference device: 510(k) K141753**

j) 510(k) submitter/holder: Degania Silicone Ltd

k) FDA Registration Number: 8030107

l) **Contact person:** Zoya Lee, Regulatory Affairs, e-mail: zoya@ds-il.com, fax: +972 4 675 5155, tel: +972 4 6755122

m) **Device Description:** AquariusÊ Gastrostomy Replacement Tube is a silicone feeding tube comprised of a double lumen tube with external proximal specific ENFit safety access port/s, external retention disk, balloon, and distal open flow-through tip. The tube is with external graduations (cm) and radiopaque marker at the distal end. The tube size and balloon capacity are clearly indicated on the shaft and pouch of each device. The tube is made without use of natural latex, BPA, or phthalates plasticizers.

n) **Indication of Use. AquariusÊ Gastrostomy Replacement Tube** is indicated for use in a well-established gastrostomy tract for feeding and/or administration of medications. May be used for gastric decompression.

o) **Technological Characteristic.** AquariusÊ Gastrostomy Replacement Tube is a substantially equivalent to the predicate unmodified device, 510(k) K**070124**. The difference between modified and unmodified/ predicate device is in the specific ENFit access port/s attached to the funnel of the unmodified device and an addition of the 10Fr size device. The design, materials, performance and safety characteristic of this specific ENFit port/s are the same as the enteral specific connection access port of the **reference device** 510(k) **K141753.**

p) **Non- clinical Summary.** Non- clinical verification of AquariusÊ Gastrostomy Replacement Tube was conducted through the risk management process According to ISO 14971:2012 and performance functionality testing. The following performance testing was conducted on the Gastrostomy Replacement Tube:

- ✓ Positive pressure liquid leak
- ✓ Stress Cracking
- ✓ Resistance to separation from axial load
- ✓ Resistance to separation from unscrewing
- ✓ Resistance to overriding
- ✓ Disconnection by unscrewing
- ✓ Flow rate
- ✓ Dimension verification
- ✓ Tensile strength
- ✓ Tensile strength of the connections of G-tube 10Fr
- ✓ Leak Test for G-tube 10F
- ✓ Simulated Gastric fluids for G-tube 10Fr
- ✓ Balloon burst volume for G-tube 10Fr
- ✓ Biocompatibility evaluation
- ✓ Shelf ï life (3 years).